

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Investigating the effect of implementation of sleep hygiene program on self-care behavior of patients with heart failure

#### Protocol summary

##### Study aim

Determining the effect of sleep hygiene program implementation on self-care behavior of heart failure patients admitted to Qaim Firozabad Hospital in 2023

##### Design

The sample size in this study is 74 people who are divided into two intervention and control groups by simple random method using Kitset software.

##### Settings and conduct

Patients admitted to Qaim Firozabad Hospital and discharged from the CCU department are placed in two groups, and the sleep health program consists of five one-and-a-half-hour sessions, three of which are face-to-face in the heart failure clinic and two in eITA Messenger.

##### Participants/Inclusion and exclusion criteria

The participants are heart failure patients Inclusion criteria: - At least one year has passed since the patient's heart failure diagnosis. - Heart failure patients of class two or three - Nativeness of heart failure patients -Being in the age group of 35 to 55 years - No use of sedative or hypnotic drugs at the time of entering the study - The ability to perform self-care - No consumption of alcoholic beverages and drugs - Expression of having sleep problems Exit criteria: - Death of the patient -Death of family members or other first degree relatives during the implementation of the study

##### Intervention groups

Depending on the intervention of sleep hygiene education and strengthening of self-care behaviors in the control group of routine discharge training

##### Main outcome variables

Management and promotion of self-care in heart failure patients.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231030059902N1**

Registration date: **2024-01-20, 1402/10/30**

Registration timing: **retrospective**

Last update: **2024-01-20, 1402/10/30**

Update count: **0**

##### Registration date

2024-01-20, 1402/10/30

##### Registrant information

###### Name

Hasan Allahyari

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3873 5374

###### Email address

allahyari814@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-12-22, 1402/10/01

##### Expected recruitment end date

2023-12-31, 1402/10/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of implementation of sleep hygiene program on self-care behavior of patients with heart failure

##### Public title

Investigating the effect of implementation of sleep hygiene program on self-care behavior of patients with heart failure

#### **Purpose**

Supportive

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

At least one year has passed since the patient's heart failure diagnosis Class II or III heart failure patients Nativeness of patients with heart failure Being in the age group of 35 to 55 years Not taking sedative or hypnotic drugs at the time of entering the study Having the ability to communicate and being literate Ability to perform self-care No consumption of alcohol and drugs Not having other chronic physical and mental disorders, including chronic kidney failure, liver failure, diabetes, or mental disorders such as major depression and other psychotic disorders. Claim to have sleep problems

##### **Exclusion criteria:**

death of the patient The death of family members or other first -class relatives during the study of the study Taking sedative or sleeping medications during intervention The creation of any adverse event that causes the patient's severe stress and anxiety at the time of study The patient's unwillingness to continue studying or not attending educational sessions for more than one session

#### **Age**

From **35 years** old to **55 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **74**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

After completing the study tool by each patient; In the next step, by giving an identification code to each of the patients and using a subsidized random selection software (random number generation kit set online), the patients participating in the study are assigned to two control and intervention groups.

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

All stages of the sleep hygiene program are performed using a comprehensive sleep hygiene booklet designed by myself, and the patient has a dynamic role in the program.

#### **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Research Ethics Committee of Jahrom University of Medical Sciences

##### **Street address**

5th floor, unit 27, Reza building, next to Afar Korosh street, Firozabad, Fars province, Iran

##### **City**

Firoozabad

##### **Province**

Fars

##### **Postal code**

7471643875

##### **Approval date**

2023-12-27, 1402/10/06

##### **Ethics committee reference number**

IR.JUMS.REC.1402.099

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Heart failure disease

#### **ICD-10 code**

I50.9

#### **ICD-10 code description**

Heart failure, unspecified

## **Primary outcomes**

### **1**

#### **Description**

self care

#### **Timepoint**

Before the intervention and one month after the intervention

#### **Method of measurement**

Jarsma's European questionnaire of self-care behaviors

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: For the intervention group, a notebook titled "Comprehensive Sleep Health Program Notebook" was prepared by the researcher, which includes five training sessions for five weeks, three sessions are held in person and two sessions are held virtually in Iranian ETA messengers. Necessary trainings are provided and Questions and answers will be held and educational sessions will include: explanation and

explanation of the phenomenon of sleep and its role in health and illness, familiarization with various types of sleep disorders and improving factors, sleep quantity and quality Daily stress management and spiritual interventions improve sleep, and face-to-face training sessions are conducted using comprehensive sleep hygiene booklets, video projectors and slides, and virtual sessions using text, video, and podcasts.

**Category**

Lifestyle

**2****Description**

Control group: There is no intervention and they receive routine training during discharge, and if the interventions performed on the intervention group are effective, all the training will be given to the control group at the end of the research.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ghaem Firozabad Hospital

**Full name of responsible person**

Hasan Allahyari

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5th floor, unit 27, Reza building, next to Afar Korosh street, Firozabad, Fars province, Iran

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Jahrom University of Medical Sciences

**Full name of responsible person**

Dr Amir Abdoli

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**Province**

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a.abdoli25@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Jahrom University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Jahrom University of Medical Sciences

**Full name of responsible person**

Hasan Allahyari

**Position**

Nursing master's student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Dr Rasol Eslamiakbar

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data**

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**Latest degree**

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**Other areas of specialty/work**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available